October 8, 2025

Genoray Co., Ltd.
℅ Suyoung Jo
General Manager
Genoray America Inc.
1220 N Simon Circle
Unit B
ANAHEIM, CA 92806

Re: K250060
Trade/Device Name: GT300; GT300-C
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: January 10, 2025
Received: September 8, 2025

Dear Suyoung Jo:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250060

Device Name
GT300; GT300-C

Indications for Use *(Describe)*
It is intended to produce 2D (panoramic, cephalometric) or 3D (Cone Beam Computed Tomography) images. It provides diagnostic details of the dental-maxillofacial, TMJ and SINUS for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

510(k) #: K250060

# 510(k) Summary

Prepared on: 2025-10-08

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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| Correspondent Contact | Mr. Suyoung Jo |
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## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | GT300;<br>GT300-C |
| Common Name | X-Ray, Tomography, Computed, Dental |
| Classification Name | Computed tomography x-ray system |
| Regulation Number | 892.1750 |
| Product Code(s) | OAS, MUH |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K200469 | PAPAYA 3D Premium & PAPAYA 3D Premium Plus | OAS, MUH |

## Device Description Summary

21 CFR 807.92(a)(4)

GT300 & GT300-C is the Diagnostic computed tomography limited view field X-ray System which consists of image acquisition modes; panorama, cephalometric, and computed tomography. It is used to capture scanned image for obtaining diagnostic information for craniofacial surgery or other treatments.

This equipment is a device that generates and controls X-rays and consists of an X-ray generator, an X-ray control unit, an X-ray support unit, and some accessories (Chinrest, Exposure switch, Temple support, Carpus Plate).

GT300 and GT300-C have same intended use, essential design and manufacturing. The GT300 can acquire panoramic and CT images, while the GT300-C can acquire panoramic, CT, and Cephalo images. The only difference is the presence or absence of the Cephalo

feature.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

It is intended to produce 2D (panoramic, cephalometric) or 3D (Cone Beam Computed Tomography) images. It provides diagnostic details of the dental-maxillofacial, TMJ and SINUS for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of GT300 & GT300-C are the same as for the predicate device.

## Technological Comparison 21 CFR 807.92(a)(6)

The proposed devices, GT300 & GT300-C, are developed based on the predicate devices, PAPAYA 3D Premium & PAPAYA 3D Premium Plus (K200469). Compared to the predicate devices, they have three differences.

First, the GT300 has one detector for panoramic/CT (Mercu0707X), while the GT300-C has two detectors. One is for panoramic/CT (Mercu0707X) and the other is for cephalometric (Extor-C).
The Extor-C (cephalometric detector) is the same detector as the predicate device (K200469), while the Mercu0707X (panoramic/CT detector) is newly applied to GT300 & GT300-C.

Second, GT300 & GT300-C can only be used with image processing software Theia. Theia has been cleared under K200469.

Third, external design has changed comparing predicate device. The emergency switch on the patient supporting area has been moved from upside to downside, and plastic enclosure design has changed.

Despite these differences, the proposed devices are identical to the predicate devices in terms of operating principle, indications for use, performance, input voltage, tube voltage, tube current, and focal spot size.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Here's a list of IEC standards the device complies with:
IEC 61223-3-7 Edition 1.0 2021-12: Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography
IEC 60601-1:2005+AMD1:2012+AMD2:2020: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 1
IEC 60601-1-2:2014+AMD1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-63:2012+AMD1:2017+AMD2:2021: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

List of FDA guidance documents used in device development:
Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff June 2025
Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff June 2023
Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff November 2017
Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff September 2016

A clinical image evaluation was conducted with the GT300 & GT300-C in accordance with the Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff issued on Sept. 1, 2016 (Section VII Clinical Considerations), and the images were reviewed by US board-certified clinician.

GT300 & GT300-C have the same indications for use as the predicate device. Any minor differences in the technical characteristics of the subject device have been successfully evaluated through the appropriate safety and performance testing.

According to the Clinical Image Evaluation Report, GT300 & GT300-C provide clinical images suitable for patient diagnosis, with image quality substantially equivalent to that of predicate device.